



## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA-HQ-OPP-2020-0375; FRL- 9472-01-OCSPP]

### Bicyclopyrone; Pesticide Tolerances

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of bicyclopyrone in or on banana; broccoli; hop, dried cones; horseradish; onion, bulb; onion, green; papaya; strawberry; sweet potato, tuber; timothy, forage; timothy, hay and watermelon. Syngenta Crop Protection, LLC., requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Objections and requests for hearings must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

**ADDRESSES:** The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2020-0375, is available at <https://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805.

Due to the public health concerns related to COVID-19, the EPA Docket Center (EPA/DC) and Reading Room is open to visitors by appointment only. For the latest status information on EPA/DC services and access, visit <https://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** Marietta Echeverria, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: [RDFRNotices@epa.gov](mailto:RDFRNotices@epa.gov).

## **SUPPLEMENTARY INFORMATION:**

### **I. General Information**

#### *A. Does this Action Apply to Me?*

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them.

Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

#### *B. How Can I Get Electronic Access to Other Related Information?*

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Office of the Federal Register's e-CFR site at <https://www.ecfr.gov/current/title-40>.

#### *C. How Can I File an Objection or Hearing Request?*

Under FFDCFA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You

must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2020-0375 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing and must be received by the Hearing Clerk on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2020-0375, by one of the following methods:

- *Federal eRulemaking Portal*: <https://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <https://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <https://www.epa.gov/dockets>.

## **II. Summary of Petitioned-For Tolerance**

In the *Federal Register* of February 25, 2021 (86 FR 11488) (FRL-10020-47), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 0F8853) by Syngenta Crop Protection, LLC, P.O. Box 18300, Greensboro, NC 27419-8300. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the herbicide bicyclopyrone, 4-hydroxy-3-{2-[(2-methoxyethoxy)methyl]-6-(trifluoromethyl)-3-pyridylcarbonyl}bicyclo[3.2.1]oct-3-en-2-one, in or on banana at 0.01 parts per million (ppm); broccoli at 0.01 ppm; garlic, bulb at 0.02 ppm, hops, dried cones at 0.04 ppm; horseradish at 0.015 ppm; onion, bulb at 0.02 ppm; onion, green at 0.05 ppm; papaya at 0.01 ppm; plantains at 0.01 ppm; strawberry at 0.01 ppm; sweet potato, roots at 0.02 ppm; timothy, forage at 0.9 ppm; timothy, hay at 1.5 ppm; and watermelon at 0.01 ppm. That document referenced a summary of the petition prepared by Syngenta Crop Protection, LLC., the registrant, which is available in the docket, <https://www.regulations.gov>. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA is establishing several tolerances at different levels than requested by the petitioner, is not establishing several petitioned for tolerances, and adjusted several commodity definitions. The reasons for these changes are explained in Unit IV.C.

### **III. Aggregate Risk Assessment and Determination of Safety**

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and

in residential settings but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for bicyclopyrone including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with bicyclopyrone follows.

In an effort to streamline its publications in the *Federal Register*, EPA is not reprinting sections of the rule that repeat what has been previously published in tolerance rulemakings for the same pesticide chemical. Where scientific information concerning a particular chemical remains unchanged, the content of those sections would not vary between tolerance rulemaking and republishing the same sections is unnecessary and duplicative. EPA considers referral back to those sections as sufficient to provide an explanation of the information EPA considered in making its safety determination for the new rulemaking.

EPA has previously published a number of tolerance rulemakings for bicyclopyrone, in which EPA concluded, based on the available information, that there is a reasonable certainty that no harm would result from aggregate exposure to bicyclopyrone and established tolerances for residues of that chemical. EPA is incorporating previously published sections from those rulemakings as described further in this rulemaking, as they remain unchanged.

### *A. Toxicological Profile*

For a discussion of the Toxicological Profile of bicyclopyrone, see Unit III.A. of the December 23, 2021, rulemaking (86-FR-72846) (FRL-9199-01-OCSP).

### *B. Toxicological Points of Departure/Levels of Concern*

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. The PODs and levels of concern have not changed from the previous rulemaking and EPA incorporates the background information in the December 23, 2021, rulemaking. A summary of the toxicological endpoints for bicyclopyrone used for human risk assessment can be found in the document titled "Bicyclopyrone: Human Health Risk Assessment for the Establishment of Permanent Tolerances for Residues in/on Bananas, Broccoli, Dry Bulb Onions, Green Onion, Hops, Horseradish, Papaya, Strawberry, Sweet Potatoes, Timothy Forage, Timothy Hay, and Watermelon" (hereinafter "Bicyclopyrone Human Health Risk Assessment") in docket ID number EPA-HQ-OPP-2020-0375 in regulations.gov.

### *C. Exposure Assessment*

Much of the exposure assessment remains the same although updates have occurred to accommodate exposures from the petitioned-for tolerance. These updates are discussed in this section; for a description of the rest of the EPA approach to and assumptions for the exposure assessment, please reference Unit III.C. of the December 23, 2021, rulemaking.

EPA's dietary exposure assessments have been updated to include the additional exposure from the new uses of bicyclopyrone on banana; broccoli; hop, dried cones; horseradish; onion, bulb; onion, green; papaya; strawberry; sweet potato, tuber; timothy, forage; timothy, hay; and watermelon (see Unit IV. C for an explanation of the differences between this list and the petitioned for tolerances). The assessment used the

same assumptions as the December 23, 2021, final rule concerning average field trial residues for registered crops, tolerance levels for the proposed crops and recently added crops, average empirical processing factors for registered crops, anticipated residues for livestock commodities, and percent crop treated (PCT) for registered crops commodities.

*D. Anticipated residue and percent crop treated (PCT) information*

Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must require pursuant to FFDCA section 408(f)(1) that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such data call-ins as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

Section 408(b)(2)(F) of FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if:

- Condition a: The data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain the pesticide residue.
- Condition b: The exposure estimate does not underestimate exposure for any significant subpopulation group.
- Condition c: Data are available on pesticide use and food consumption in a particular area, and the exposure estimate does not understate exposure for the population in such area.

In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by FFDCA section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The chronic dietary assessment incorporated the following average PCT estimates: barley, 1%; field corn, 10%; sweet corn, 5%; pop corn, 10% (used the higher of the corn PCT); and wheat, 5% (used spring wheat PCT which was higher than winter wheat PCTs). An estimate of 100% crop treated was used for all other commodities. The PCT for livestock commodities is based on the PCT value for the livestock feed item used in the dietary burden with the highest percent crop treated (field corn, 10%).

In most cases, EPA uses available data from the United States Department of Agriculture/National Agricultural Statistics Service (USDA/NASS), proprietary market surveys, and the California Department of Pesticide Regulation (CalDPR) Pesticide Use Reporting (PUR) for the chemical/crop combination for the most recent 10 years. EPA uses an average PCT for chronic dietary risk analysis and a maximum PCT for acute dietary risk analysis. The average PCT figure for each existing use is derived by combining available public and private market survey data for that use, averaging across all observations, and rounding to the nearest 5%, except for those situations in which the average PCT is less than 1% or less than 2.5%. In those cases, the Agency would use less than 1% or less than 2.5% as the average PCT value, respectively. The maximum PCT figure is the highest observed maximum value reported within the most recent 10 years of available public and private market survey data for the existing use and rounded up to the nearest multiple of 5%, except where the maximum PCT is less than 2.5%, in which case, the Agency uses less than 2.5% as the maximum PCT.

The Agency believes that the three conditions discussed in Unit III.C.1. iv have been met. With respect to Condition a, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions b and c, regional consumption information and consumption information for significant subpopulations is taken into account through

EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available reliable information on the regional consumption of food to which bicyclopyrone may be applied in a particular area.

*Dietary exposure from drinking water.* EPA has revised the bicyclopyrone Drinking Water Assessment (DWA) since the December 23, 2021, rule. The 2016 DWA for bicyclopyrone (USEPA, 2016, DP Barcode 428614) recommended moving forward with estimated drinking water concentrations (EDWCs) for a groundwater scenario that occurred in a wheat and barley growing area and move away from the existing EDWCs based on a simulation resulting in the highest groundwater EDWC. The Human Health Risk Assessment (USEPA, 2022, DP Barcode 459563) used the highest groundwater EDWCs from the previous 2016 DWA. The maximum acute and chronic/cancer surface water and groundwater EDWCs associated with bicyclopyrone use were 7.61 parts per billion (ppb) for the maximum acute and 6.66 ppb, for the maximum chronic/cancer.

*Non-occupational exposure.* There are no new residential (non-occupational) exposures associated with the new proposed uses and bicyclopyrone is not registered for any use patterns that would result in residential exposure.

*Cumulative exposure.* For a discussion of the cumulative exposure assessment of bicyclopyrone, see Unit III.C.4 of the December 23, 2021, rulemaking.

*Safety factor for infants and children.* EPA continues to conclude that there are reliable data to support the reduction of the Food Quality Protection Act (FQPA) safety

factor. See Unit III.D of the December 23, 2021 rulemaking for a discussion of the Agency's rationale for that determination.

*Aggregate risks and determination of safety.* EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute population-adjusted dose (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate points of departure to ensure that an adequate margin of exposure exists.

An acute dietary exposure assessment was not conducted as toxicological effects attributable to a single dose were not identified. Chronic dietary risks are below the Agency's level of concern of 100% of the cPAD: the population subgroup with the highest exposure estimate was all infants at 16% of the cPAD. Bicyclopyrone is classified as "Suggestive Evidence of Carcinogenic Potential". However, because the Agency has determined that the chronic reference dose will be protective of any potential cancer risk and there are no chronic risks that exceeds the Agency's level of concern, EPA concludes that there is not a concern for cancer risk from exposure to bicyclopyrone. There are no registered or new uses of bicyclopyrone that would result in residential exposure, therefore the aggregate risk estimates are equivalent to the chronic dietary (food and water) risk estimates and are not of concern.

Based on these risk assessments and the information described above, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to bicyclopyrone residues. More detailed information about the Agency's analysis can be found in the Bicyclopyrone Human Health Risk Assessment in docket ID number EPA-HQ-OPP-2020-0373 in regulations.gov at <https://www.regulations.gov>.

## **IV. Other Considerations**

### *A. Analytical Enforcement Methodology*

For a discussion of the available analytical enforcement method, see Unit IV.A of the December 23, 2021, rulemaking.

### *B. International Residue Limits*

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDC section 408(b)(4).

The Codex has not established a MRL for residues of bicyclopyrone in/on bananas, broccoli, dry bulb onions, timothy forage or hay, green onion, hops, horseradish, papaya, strawberry, sweet potato, or watermelon.

### *C. Revisions to Petitioned-For Tolerances*

FFDCA section 408(d)(4)(A)(i) permits the Agency to finalize a tolerance that varies from that sought by the petition. The petitioner initially requested to include tolerances for both banana and plantain; however, a separate tolerance is not required for plantain per 40 CFR 180.1(g). Therefore, the Agency is only finalizing a tolerance for banana. The petitioner also requested to include tolerances for both garlic and onion, bulb; however, a separate tolerance is not required for garlic per 40 CFR 180.1(g). Therefore, the Agency is only finalizing a tolerance for onion, bulb.

The proposed commodity definitions for hops, dried cones; sweet potato, roots; have been modified to hop, dried cones; sweet potato, tuber, respectively, in order be consistent with Agency nomenclature.

The petitioner initially requested a tolerance of 0.9 ppm for timothy, forage and 1.5 ppm for timothy, hay. The petitioner appears to have calculated the requested

tolerance value using input residue values from the forage and hay decline trials with a longer preharvest intervals (PHI), which would underestimate the resulting residues. The Agency used the residue values from the decline trial that had the shortest PHI. The Agency deems it appropriate to use the more conservative (i.e., results with the highest residue value) approach and as a result produced a recommended tolerance of 1.5 ppm for timothy, forage and 2 ppm for timothy, hay when entered into the OECD calculator.

The proposed commodity for horseradish tolerance has also been modified to be set at the respective limit of quantitation (LOQs), as there were no residues detected.

## **V. Conclusion**

Therefore, tolerances are established for residues of bicyclopyrone, 4-hydroxy-3-[[2-[(2-methoxyethoxy)methyl]-6-(trifluoromethyl)-3-pyridinyl]carbonyl]bicyclo[3.2.1]oct-3-en-2-one, including its metabolites and degradates in or on banana at 0.01 ppm; broccoli at 0.01 ppm; hop, dried cones at 0.04 ppm; horseradish at 0.02 ppm; onion, bulb at 0.02 ppm; onion, green at 0.05 ppm; papaya at 0.01 ppm; strawberry at 0.01 ppm; sweet potato, tuber at 0.02 ppm; timothy, forage at 1.5 ppm; timothy, hay at 2 ppm; and watermelon at 0.01 ppm.

## **VI. Statutory and Executive Order Reviews**

This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This action does not contain any

information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or Tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or Tribal Governments, on the relationship between the National Government and the States or Tribal Governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian Tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

## **VII. Congressional Review Act**

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the *Federal Register*. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

**List of Subjects in 40 CFR Part 180**

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: March 9, 2022.

**Marietta Echeverria,**

*Acting Director, Registration Division, Office of Pesticide Programs.*

Therefore, for the reasons stated in the preamble, EPA is amending 40 CFR chapter I as follows:

**Part 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD**

1. The authority citation for part 180 continues to read as follows:

**Authority:** 21 U.S.C. 321(q), 346a and 371.

2. In § 180.682 amend Table 1 to Paragraph (a) (1) by adding in alphabetical order the entries “Banana”; “Broccoli”; “Hop, dried cones”; “Horseradish”; “Onion, bulb”; “Onion, green”; “Papaya”; “Strawberry”; “Sweet potato, tuber”; “Timothy, forage”; Timothy, hay”; and “Watermelon” to read as follows:

**§ 180.682 Bicyclopyrone; tolerances for residues.**

(a) \* \* \*

(1) \* \* \*

Table 1 to Paragraph (a)(1)

Commodity	Parts per million
Banana	0.01
* * * * *	
Broccoli	0.01
* * * * *	
Hop, dried cones	0.04
* * * * *	
Horseradish	0.02
* * * * *	
Onion, bulb	0.02
Onion, green	0.05
Papaya	0.01
* * * * *	
Strawberry	0.01
* * * * *	
Sweet potato, tuber	0.02
Timothy, forage	1.5
Timothy, hay	2
* * * * *	
Watermelon	0.01
* * * * *	

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